body including a base, a spacer having first and second ends that are longitudinally spaced apart, said first end being integral with said base, and a pair of flexible handles integral with said second end of said spacer, the flexible handles adapted to be grasped for insertion of said needle device into and removal of said needle device from said patient.

Please cancel claims 2 and 10 without prejudice.

Please amend claim 11 as follows:

11. (Amended). The needle device according to claim 1 wherein a first portion of said L-shaped needle extends from and is substantially perpendicular to said base.

REMARKS

Reconsideration and removal of the grounds for rejection are respectfully requested. Claims 1-16 were in the application, claims 1 and 11 were amended, claims 2 and 10 have been cancelled.

Claims 1, 2 and 3 were rejected under 35 U.S.C. §102(b) as being anticipated by Kay et al.

Claim 1 has been amended to include the limitations of claims 2 and 10 therein, rendering this rejection moot as to amended claim 1.

Claims 1, 2 and 3 were also rejected under 35 U.S.C. §102(b) as being anticipated by Raines.

Claim 1 has been amended to include the limitations of claims 2 and 10 therein, rendering this rejection moot as to amended claim 1.

Claims 1-6, 10-13, 15 and 16 were rejected under 35 U.S.C. §102(b) as being anticipated by Marcus, U.S. Patent No. 4,813,939.

To have ancticipation, each and every element of the claim must be found in a single prior art reference. W.L. Gore & Assoc. Inc. v. Garlock, Inc., 220 U.S.P.Q. 303 (Fed. Cir. 1983). All the limitations in the claims must be found in the reference, since the claims measure the invention. In re Lange, 209 U.S.P.Q. 288, 293 (CCPA 1981).

Marcus discloses a winged infusion needle apparatus with an L-shaped needle. However, Marcus fails to show a body which includes a base, a spacer having first and second ends

longitudinally spaced apart, the first end being integral with the base, and a pair of flexible handles integral with the second end of the spacer. Instead, Marcus has a winged portion separate from the rest of the needle apparatus. The wing members are hinged to a central section and to grasp the wings, the wing members are rotated about their hinges. However the wing members are necessarily rigid to ensure rotation only along the hinges. As the wing members are very small, they do not meet when the apparatus in grasped, making it difficult to grip, as the fingers may slide off the wing edges. Fig. 6 clearly shows that the wings are rigid when grasped.

On the other hand, the flexible handles of the present invention allow gripping without such slippage.

As each and every element of amended claim 1 is not found in Marcus, claim 1 and the claims dependent therefrom are not anticipated by Marcus.

Claims 1-16 were rejected under 35 U.S.C. §103(a) as being obvious over Marcus in view of Kay.

It is not within the framework of 35 U.S.C. §103(a) to pick and choose from the prior art only so much as will support a holding of obviousness to the exclusion of other parts for a full appreciation of what the prior art teaches or suggests, as hindsight is not the test. In re Wesslau, 353 F.2d 238 (CCPA 1965). Both the suggestion and expectation of success must be found in the prior art, not in the applicant's disclosure. In re Dow Chem. Co, 837 F.2d 469 (Fed. Cir. 1988). The mere fact that the prior art could be modified does not make the modification obvious unless the prior art suggests the desirability of the modification. B.F. Goodrich v. Aircraft Braking Sys. Corp., 72 F.3d 1577, 1582 (Fed. Cir. 1996).

As discussed above, Marcus does not disclose, teach or suggest a body including a base, a spacer integral with the base and pair of flexible handles adapted to be grasped for insertion of the needle device into and removal of the device from the patient.

Kay et al teaches a device in which the handles must be removed from the remainder of the device when the device is taped into place on the patient. Since the handles are removed, they can be misplaced a lost.

While the handles of Kay are molded separately, and are rigid for grasping, the device of

the applicants invention is integral, that is, the handles, spacer and base are molded together, not separately, and the flexible handles ease the grasping during insertion of the needle into the patient and during removal, which is not taught or suggested in the prior art cited by the examiner.

The spacer, located between the base and flexible handles additionally inhibits contact between the handles and the patient's skin to prevent infection by spacing the handles away from the wound site when the device is taped down on the patient.

As there is no teaching suggestion or incentive supporting the combination, the combination is improper. Even if properly made, the combination fails to teach or suggest the applicant's invention, utilizing the integral construction flexible handles, and claim 1, and the claims dependent therefrom are not obvious in view of the cited art.

Based on the above amendments and remarks, favorable consideration and allowance of the application is respectfully requested. However, should the examiner believe that direct contact with the applicant's attorney would advance the prosecution of the application, the examiner is invited to telephone the undersigned at the number given below.

Respectfully submitted,

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MARKED-UP CLAIMS

1. A needle device for percutaneous drug delivery to a patient, the device comprising:

a substantially L-shaped, hollow needle for drug delivery therethrough, the needle including a needle end; and

a body secured to said needle and longitudinally spaced from said needle end, said body including [an integral] a base, a spacer having first and second ends that are longitudinally spaced apart, said first end being integral with said base, and a pair of flexible handles integral with said second end of said spacer, the flexible handles adapted to be grasped for insertion of said needle device into and removal of said needle device from said patient.

11. The needle device according to claim 1 [10] wherein a first portion of said L-shaped needle extends from and is substantially perpendicular to said base.